



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/649,582

08/27/2003

James Brugger

53951-093

8937

21890

7590

10/16/2006

PROSKAUER ROSE LLP
PATENT DEPARTMENT
1585 BROADWAY
NEW YORK, NY 10036-8299

EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/649,582

Applicant(s)

BRUGGER ET AL.

Examiner

Leslie R. Deak

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-10,12,14,16-19 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-10,12,14,16-19,21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27-August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,476,592 to Simard in view of US 6,716,356 to Collins et al.

In the specification and the figures, Simard discloses the apparatus substantially as claimed by applicant. With regard to claims 1 and 6, Simard discloses a hemofiltration apparatus with a fluid circuit with a blood path 5, 6, filtrate line 10 connected 3 across a porous membrane 4 to the blood portion 2, and a replacement fluid line 22. The entirety of the replacement fluid is passed through in-line sterile filter 15, 24 for removing pyrogens (see FIG 1, column 2, lines 45-67, column 3, lines 1-20). The circuit comprises a drip chamber 8 with two inlets or connectors that allow the filtered blood (which may comprise a replacement fluid, since it is replacing the fluid drawn into the circuit) and the substitute or replacement fluid to be connected to the return line 6. The device further comprises pump 7 in the blood draw line 5, pump 14 in filtrate line 10, and pump 23 in replacement fluid line 22.

Simard fails to disclose that the replacement fluid portion has a plurality of connectors joined to flow through the sterilizing filter and a common inlet to the replacement fluid portion. However, Collins discloses an extracorporeal fluid treatment

Art Unit: 3761

circuit with replacement fluids that flow from sources 102, 152, and 150 that are connected to the replacement fluid line (see FIG 1, column 3, lines 25-33). Replacement fluid pump 158 pulls fluid from the various lines and pushes it through replacement fluid 160 (see column 5, lines 47-61). Multiple containers are connected to the replacement fluid line to adjust the pH of the replacement fluid (see column 4, lines 20-25).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add multiple fluid lines and connectors in the replacement fluid portion as disclosed by Collins to the extracorporeal treatment system disclosed by Simard in order to adjust the composition of the replacement fluid, as taught by Collins (see column 4, lines 20-25).

Applicant presents claims drawn to a "kit" of the claimed components. However, applicant has not set forth in the specification what, exactly, comprises the kit, other than the claimed components. Therefore, examiner has interpreted the claims to mean that the claimed components comprise the claimed kit.

With regard to claim 7, Simard discloses filtrate line with pump 14, blood line with pump 7, and replacement fluid line with pump 23, each of which are configured to interact with one another to move fluids through the lines (see FIG 1, column 2, line 45 through column 3, line 15).

3. Claims 3, 5, 8-10, 12, 14, 16-19, and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,476,592 to Simard in view of US 6,716,356 to Collins, further in view of US 5,441,636 to Chevallet et al.

In the specification and figures, Simard and Collins disclose the apparatus substantially as claimed by applicant (see rejection above) with the exception of a cassette, support or tray that supports the fluid circuit, filter, and other components.

With regard to claims 3, 8, Chevallet discloses a fluid handling plate or tray 20 that may comprise multiple interconnected fluid circuits, including a blood supply and return line, a dialyzer, diasylate circuit, and a replacement fluid circuit (see FIGS 1-2, column 4, lines 3-67). The placement of all the components in a support or cassette allows for reduced pre and post-procedure handling and connection, reducing connection errors, and lends itself to sterile packaging and safe disposal (see column 2, lines 1-8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the fluid lines, filters, and pumps disclosed by Simard and Collins in a support cassette as disclosed by Chevallet, in order to reduce preparation time and errors, as taught by Chevallet (see column 2, lines 1-8).

With regard to claim 5, Chevallet specifically discloses that the replacement fluid circuit 80 comprises bag spike 81 for selective connection to a fluid source (see column 4, lines 56-65). Simard and Collins teach a fluid circuit with a replacement fluid circuit comprising a plurality of connections to multiple fluid sources and Chevallet teaches the use of a spike to make such a connection. The combination of the disclosures suggest that it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of bag spikes as connectors to multiple fluid sources, since Chevallet teaches that such a connection is well-known in the art (see column 4, lines 56-63).

With regard to claims 9 and 12, Simard and Collins disclose an extracorporeal fluid circuit with an inline sterile filter in the replacement fluid line and multiple connections to multiple fluid sources, as set forth above. Chevallet specifically discloses a support plate or cartridge 20 with a plurality of fluid circuits mounted therein (see column 4, lines 3-25). The fluid circuits include a dialyzer or filter 40 with a blood circuit portion 50, 70, connected to the filter, as well as a replacement fluid circuit 80 and a waste fluid circuit 100 (see column 4, line 3 through column 5 line 23).

With regard to claim 10, Simard discloses a venous line connected to a patient access (see column 2, lines 50-55) and illustrates filter 15 as disposed between fluid source 11 and blood circuit 5/6, with the replacement fluid line 22 connected via drip chamber 8 to venous return line 6 (see FIG 1).

With regard to claim 14, Chevallet specifically discloses that the replacement fluid circuit 80 comprises bag spike 81 for selective connection to a fluid source (see column 4, lines 56-65). Simard and Collins teach a fluid circuit with a replacement fluid circuit comprising a plurality of connections to multiple fluid sources and Chevallet teaches the use of a spike to make such a connection. The combination of the disclosures suggest that it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of bag spikes as connectors to multiple fluid sources, since Chevallet teaches that such a connection is well-known in the art (see column 4, lines 56-63).

With regard to claim 16, Simard discloses filtrate line with pump 14, blood line with pump 7, and replacement fluid line with pump 23, each of which are configured to

interact with one another to move fluids through the lines (see FIG 1, column 2, line 45 through column 3, line 15).

With regard to claim 17, Chevallet illustrates that support or tray 20 comprises connectors 34 that align the pumping tube portions such that they may engage with roller pumps or actuators 112, 113, 114, 115 on a treatment module.

With regard to claims 18, 21, 23, Simard and Collins disclose an extracorporeal fluid circuit with an inline sterile filter in the replacement fluid line and multiple connections to multiple fluid sources, as set forth above. Chevallet specifically discloses a support plate or cartridge 20 with a plurality of fluid circuits mounted therein (see column 4, lines 3-25). The fluid circuits include a dialyzer or filter 40 with a blood circuit portion 50, 70 connected to the filter, wherein the blood circuit may be configured for both venous and arterial blood supply and return arrangements, meeting the limitations of the claim (see column 3, lines 23-35). The fluid circuit further includes a replacement fluid circuit 80 connected to a replacement solution and an outlet end optionally connected to blood return circuit (see column 4, lines 56-68).

With regard to claim 19, Simard discloses that the filter has a porosity of $0.22\mu\text{m}$ (see column 3, lines 56-62), meeting the limitations of the claim.

With regard to claim 22, Chevallet specifically discloses that the replacement fluid circuit 80 comprises bag spike 81 for selective connection to a fluid source (see column 4, lines 56-65). Simard and Collins teach a fluid circuit with a replacement fluid circuit comprising a plurality of connections to multiple fluid sources and Chevallet teaches the use of a spike to make such a connection. The combination of the

Art Unit: 3761

disclosures suggest that it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of bag spikes as connectors to multiple fluid sources, since Chevallet teaches that such a connection is well-known in the art (see column 4, lines 56-63).

With regard to claim 24, Simard discloses filtrate line with pump 14, blood line with pump 7, and replacement fluid line with pump 23, each of which are configured to interact with one another to move fluids through the lines (see FIG 1, column 2, line 45 through column 3, line 15).

With regard to claim 25, Chevallet illustrates that support or tray 20 comprises connectors 34 that align the pumping tube portions such that they may engage with roller pumps or actuators 112, 113, 114, 115 on a treatment module.

Response to Arguments

4. Applicant's amendment filed 22 August 2006 has been entered and considered.
5. Applicants arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

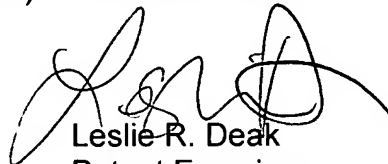
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761
2 October 2006

TATYANA ZAIJUKAEVA
SUPERVISORY EXAMINER

